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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: **Madison et al.**  
Serial No.: 09/776,191  
Filed: February 2, 2001  
For: **NUCLEIC ACID MOLECULES ENCODING  
TRANSMEMBRANE SERINE PROTEASES,  
THE ENCODED PROTEINS AND METHODS  
BASED THEREON**  
Art Unit: 1614  
Examiner: Unassigned

TRANSMITTAL LETTER

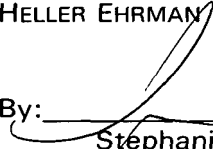
Commissioner for Patents  
Washington, D.C. 20231

Sir:

Transmitted herewith is an Information Disclosure Statement, Forms PTO-1449 (21 pages), and the cited references for filing in connection with the above-identified application. Because this Information Disclosure Statement is filed prior to receipt of a First Office Action on the merits in the above-referenced application, no fee is due. However, should it be determined that a fee for filing these papers is required, the Commissioner is authorized to charge Deposit Account No. 50-1213, as stated below:

( X )                      The Commissioner is hereby authorized to charge any fees that may be due under 37 C.F.R. §§1.16-1.17 in connection with this paper or with this application during its entire pendency to Deposit Account No. 50-1213. A duplicate of this sheet is enclosed.

Respectfully submitted,  
HELLER EHRMAN WHITE & MCAULIFFE LLP

By:   
Stephanie L. Seidman  
Registration No. 33,779

**Dated: August 1, 2001**  
Attorney Docket No.: 24745-1607  
**Address all correspondence to:**  
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**INFORMATION DISCLOSURE STATEMENT IN ACCORDANCE  
WITH 37 C.F.R. §§ 1.97-1.98**

Commissioner for Patents  
Washington, D.C. 20231

Dear Sir:

Since this Information Disclosure Statement is filed before the receipt of a first Office Action on the merits for the above-captioned application, no filing fee is due. If it is determined that a fee is due, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 50-1213.

In accordance with the duty of disclosure imposed by 37 C.F.R. §1.56 to inform the Patent Office of all references known by Applicant or Applicant's representative that may be material to the examination of the subject application, Applicant's representative hereby provides this Information Disclosure Statement that is prepared in accordance with 37 C.F.R. §§1.97-1.98. The Forms PTO-1449 (21 pages) and cited reference are provided herewith.

**U.S.S.N. 09/776,191**  
**MADISON, *et al.***  
**IDS**

The documents listed on the Forms PTO-1449 and supplied herewith are in the English language with the exception if Item HR. Item HR is a Japanese language reference by Shiozaki *et al.* and includes an English Language abstract. Hence, in accordance with the requirements of 37 C.F.R. §1.98, as amended effective March 16, 1992, no further explanation of the listed items is necessary.

Applicant also makes known to the Examiner the following U.S. applications which are commonly owned and/or have one or more inventors in common.

<u>U.S.S.N.(App. no.)</u>	<u>Filing Date</u>	<u>Docket No.</u>
09/580,535	05/26/00	1604B
09/657,986	09/08/00	
09/716,036	11/17/00	1604C
09/717,473	11/20/00	1605
60/255,221	12/12/00	P1606
09/776,191	02/02/01	1607
60/293,267	05/23/01	P1611
60/275,592	03/13/01	P1613
60/278,166	03/22/01	P1614
60/279,228	03/27/01	P1615
60,291,501	05/15/01	P1615B
60/291,001	05/14/01	P1616

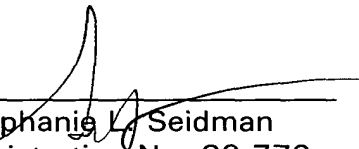
<u>Int'l Appln. No.</u>	<u>Filing Date</u>	<u>Docket No.</u>
PCT/US01/03471	02/02/01	1607PC

Although these documents are made known to the Patent and Trademark Office in compliance with Applicant's duty of disclosure, such disclosure is not to be construed as an admission by Applicant or Applicant's representative that any of the references, singly or in any combination thereof, is effective as prior art against the subject application. In accordance with 37 C.F.R. §1.97(h), the filing of this Supplemental Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 C.F.R. §1.56(b) exists.

U.S.S.N. 09/776,191  
MADISON, *et al.*  
IDS

Applicant respectfully requests that the Examiner review the foregoing reference and it be made of record in the file history of the above-captioned application.

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FORM PTO-1449 (Modified)	ATTY. DOCKET NO. 24745-1607	SERIAL NO. 09/776,191
	APPLICANT MADISON et al.	
	FILING DATE February 2, 2001	GROUP 1614

LIST OF PATENTS AND PUBLICATIONS FOR  
APPLICANT'S INFORMATION DISCLOSURE  
STATEMENT

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUB CLASS	FILING DATE
	A	4	1	7	9	3	3	7	12/18/79	Davis <i>et al.</i>	435	181	07/28/77
	B	4	3	0	1	1	4	4	11/17/81	Iwashita <i>et al.</i>	424	78	07/10/80
	C	4	4	9	6	6	8	9	01/29/85	Mitra	525	54.1	12/27/83
	D	4	6	4	0	8	3	5	02/03/87	Shimizu <i>et al.</i>	424	94	10/28/83
	E	4	6	7	0	4	1	7	06/02/87	Shimizu <i>et al.</i>	514	6	02/21/86
	F	4	7	9	1	1	9	2	12/13/88	Nakagawa <i>et al.</i>	530	399	06/18/87
	G	4	9	8	0	2	8	6	12/25/90	Morgan <i>et al.</i>	435	172.3	01/03/89
	H	5	2	2	5	5	3	9	07/06/93	Winter	530	387.3	10/25/91
	I	5	2	7	0	1	7	0	12/14/93	Schatz <i>et al.</i>	435	7.37	10/16/91
	J	4	9	5	2	4	9	6	08/28/90	Studier <i>et al.</i>	435	91	12/29/86
	K	5	2	1	5	8	9	9	06/01/93	Dattagupta	435	6	08/23/90
	L	5	4	3	6	1	2	8	07/25/95	Harpold <i>et al.</i>	435	6	01/27/93
	M	5	4	8	2	8	4	8	01/09/96	Dickson <i>et al.</i>	435	219	02/22/94
	N	5	6	1	2	4	7	4	03/18/97	Patel	536	27.14	06/30/94
	O	5	7	9	2	6	1	6	08/11/98	Persico <i>et al.</i>	435	7.21	06/05/95
	P	5	9	7	2	6	1	6	10/26/99	O'Brien <i>et al.</i>	435	6	02/20/98
	Q	6	1	2	1	2	3	8	09/19/00	Dower <i>et al.</i>	514	13	02/03/99

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUB CLASS	Translation Yes No	
	R	0	0	1	2	7	0	8	03/09/00	PCT				
	S	0	0	5	2	0	4	4	09/08/00	PCT				
	T	0	0	5	3	2	3	2	09/14/00	PCT				
	U	0	0	6	8	2	4	7	11/16/00	PCT				

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	V	0	0	7	8	9	6	1	12/28/00	PCT A1				
	W	8	8	0	9	8	1	0	12/15/88	PCT				
	X	8	9	1	0	1	3	4	11/02/89	PCT				
	Y	9	0	1	1	3	6	4	10/04/90	PCT				
	Z	9	2	0	6	1	8	0	04/16/92	PCT				
	AA	9	2	2	0	3	1	6	11/26/92	PCT				
	AB	9	2	2	2	6	3	5	12/23/92	PCT				
	AC	9	3	1	4	1	8	8	07/22/93	PCT				
	AD	9	3	2	0	2	2	1	10/14/93	PCT				
	AE	9	4	0	8	5	9	8	04/28/94	PCT				
	AF	9	5	1	1	7	5	5	05/04/95	PCT				
	AG	9	5	3	4	3	2	6	12/21/95	PCT				

OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

AH	Abraham <i>et al.</i> , "Immunochemical Identification of the Serine Protease Inhibitor $\alpha_1$ -Antichymotrypsin in the Brain Amyloid Deposits of Alzheimer's Disease", <i>Cell</i> , <u>52</u> :487-501; (1988)
AI	Alam <i>et al.</i> , "Reporter Genes: Application to the Study of Mammalian Gene Transcription", <i>Anal. Biochem.</i> , <u>188</u> :245-254; (1990)
AJ	Alonso <i>et al.</i> , "Effects of synthetic urokinase inhibitors on local invasion and metastasis in a murine mammary tumor model", <i>Breast Cancer Res. Treat.</i> , <u>40</u> :209-223; (1996)
AK	Appel <i>et al.</i> , "The <i>Drosophila</i> Stubble-stubblod gene encodes an apparent transmembrane serine protease required for epithelial morphogenesis", <i>Proc. Natl. Acad. Sci. U.S.A.</i> , <u>90</u> :4937-4941; (1993)
AL	Avery <i>et al.</i> , "Systemic Amiloride Inhibits Experimentally Induced Neovascularization", <i>Arch. Ophthalmol.</i> , <u>108</u> :1474-1476; (1990)

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## OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

AM	Brains <i>et al.</i> , "Effects of LEX032, a novel recombinant serine protease inhibitor, on <i>N</i> <sup>6</sup> -nitro-L-arginine methyl ester induced leukocyte-endothelial cell", <i>Eur. J. Pharmacol.</i> , <u>356</u> :67-72; (1998)
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AO	Batra <i>et al.</i> , "Insertion of Constant Region Domains of Human IgG <sub>1</sub> Into CD4-PE40 Increases Its Plasma Half-life", <i>Molecular Immunol.</i> , <u>30</u> (4):379-386; (1993)
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AR	Berger <i>et al.</i> , "Structure of the mouse gene for the serine protease inhibitor neuroserpin (PI12)", <i>Gene</i> , <u>214</u> :25-33; (1998)
AS	Benoist <i>et al.</i> , " <i>In vivo</i> sequence requirements of the SV40 early promoter region", <i>Nature</i> , <u>290</u> :304-310; (1981)
AT	Billström <i>et al.</i> , "The Urokinase Inhibitor p-Aminobenzamidine Inhibits Growth of a Human Prostate Tumor in SCID Mice", <i>Int. J. Cancer</i> , <u>61</u> :542-547; (1995)
AU	Blanton <i>et al.</i> , "Characterization of a native and recombinant <i>Schistosoma haematobium</i> serine protease inhibitor gene product", <i>Mol. Biochem. Parasitol.</i> , <u>63</u> :1-11; (1994)
AV	Boesen <i>et al.</i> , "Circumvention of chemotherapy-induced myelosuppression by transfer of the <i>mdr1</i> gene", <u>6</u> :291-302; (1994)
A W	Bourinbaier <i>et al.</i> , "Effect of Serine Protease Inhibitor, <i>N</i> - $\alpha$ -Tosyl-L-lysyl-Chloromethyl Ketone (TLCK), on Cell-Mediated and Cell-Free HIV-1 Spread", <i>Cell. Immuno.</i> , <u>155</u> :230-236; (1994)
AX	Bout <i>et al.</i> , "Lung Gene Therapy: <i>In Vivo</i> Adenovirus-Mediated Gene Transfer to Rhesus Monkey Airway Epithelium", <i>Human Gene Therapy</i> , <u>5</u> :3-10; (1994)
AY	Braunwalder <i>et al.</i> , "Application of Scintillating Microtiter Plates to Measure Phosphopeptide Interactions with the GRB2-SH2 Binding Domain", <i>J. Biomol. Screening</i> , <u>1</u> (1):23-26; (1996)
AZ	Brinster <i>et al.</i> , "Regulation of metallothionein-thymidine kinase fusion plasmids injected into mouse eggs", <i>Nature</i> , <u>296</u> :39-42; (1982)

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BA	Brooks <i>et al.</i> , "Use of the 10-Day-Old Chick Embryo Model for Studying Angiogenesis", <i>Methods in Molecular Biology</i> , <u>129</u> :257-269; (1999)
BB	Capecchi <i>et al.</i> , "Altering the Genome by Homologous Recombination", <i>Science</i> , <u>244</u> :1288-1292; (1989)
BC	Chait <i>et al.</i> , "Weighing Naked Proteins: Practical, High-Accuracy Mass Measurement of Peptides and Proteins", <i>Science</i> , <u>257</u> :1885-1894; (1992)
BD	Chen <i>et al.</i> , "IL-1 $\beta$ Induces Serine Protease Inhibitor 3 (SPI-3) Gene Expression in Rat Pancreatic $\beta$ -Cells. Detection by Differential display of Messenger RNA", <i>CYTOKINE</i> , <u>11(11)</u> :856-862; (1999)
BE	Chen <i>et al.</i> , "Interaction of Phosphorylated Fc $\gamma$ R1y Immunoglobulin Receptor Tyrosine Activation Motif-based Peptides with Dual and Single SH2 Domains of p72 <sup>syk</sup> ", <i>J. Biol. Chem.</i> , <u>271(41)</u> :25308-25315; (1996)
BF	Cline <i>et al.</i> , "Perspectives for Gene Therapy: Inserting New Genetic Information into Mammalian Cells by Physical Techniques and Viral Vectors", <i>Pharmac. Ther.</i> , <u>29</u> :69-92; (1985)
BG	Clowes <i>et al.</i> , "Long-Term Biological Response of Injured Rat Carotid Artery Seeded with Smooth Muscle Cells Expressing Retrovirally Introduced Human Genes", <i>J. Clin. Invest.</i> , <u>93</u> :644-651; (1994)
BH	Cole <i>et al.</i> , in <u>Monoclonal Antibodies and Cancer Therapy</u> , "The EBV-Hybridoma Technique and Its Application to Human Lung Cancer", <i>Alan R. Liss, Inc.</i> , pages 77-96; (1985)
BI	Coombs <i>et al.</i> , "Revisiting Catalysis by Chymotrypsin Family Serine Proteases Using Peptide Substrates and Inhibitors with Unnatural Main Chains", <i>J. Biol. Chem.</i> , <u>274(34)</u> :24074-24074; (1999)
BJ	Coombs <i>et al.</i> , "Substrate specificity of prostate-specific antigen (PSA)", <i>Chem. Biol.</i> , <u>5(9)</u> :475-488; (1998)
BK	Coombs <i>et al.</i> , "Directing Sequence-Specific Proteolysis to New Targets. The Influence Of Loop Size And Target Sequence Of Selective Proteolysis By Tissue-Type Plasminogen Activator And Urokinase-Type Plasminogen Activator", <i>J. Biol. Chem.</i> , <u>273(8)</u> :4323-4328; (1998)
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	BM	Cote <i>et al.</i> , "Generation of human monoclonal antibodies reactive with cellular antigens", <i>Proc. Natl. Acad. Sci. U.S.A.</i> , <u>80</u> :2026-2030; (1983)
	BN	Cotten <i>et al.</i> , "Receptor-Mediated Transport of DNA into Eukaryotic Cells", <i>Meth. Enzymol.</i> , <u>218</u> :619-645; (1993)
	BO	Crowley <i>et al.</i> , "Prevention of metastasis by inhibition of the urokinase receptor", <i>Proc. Natl. Acad. Sci. U.S.A.</i> , <u>90</u> :5021-5025; (1993)
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	BQ	Cwirla <i>et al.</i> , "Peptides on phage: A vast library of peptides for identifying ligands", <i>Proc. Natl. Acad. Sci. U.S.A.</i> , <u>87</u> :6378-6382; (1990)
	BR	Delaria <i>et al.</i> , "Characterization of Placental Bikunin, a Novel Human Serine Protease Inhibitor", <i>J. Biol. Chem.</i> , <u>272</u> (18):12209-12214; (1997)
	BS	Dillon, "Regulating gene expression in gene therapy", <i>TIBTECH</i> , <u>11</u> (5):167-173; (1993)
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	BV	Dower <i>et al.</i> , "The Search for Molecular Diversity (II): Recombinant and Synthetic Randomized Peptide Libraries", <i>An. Rep. Med. Chem.</i> , <u>26</u> :271-280; (1991)
	BW	Dryjanski <i>et al.</i> , " <i>N</i> -Tosyl-L-phenylalanine Chloromethyl Ketone, a Serine Protease Inhibitor, Identifies Glutamate 398 at the Coenzyme-Binding Site of Human Aldehyde Dehydrogenase. Evidence for a Second "Naked Anion" at the Active Site", <i>Biochem.</i> , <u>37</u> (40):14151-14156; (1998)
	BX	Dufer <i>et al.</i> , "Differential Effect of the Serine Protease Inhibitor Phenyl Methyl Sulfonyl Fluoride on Cytochemically Detectable Esterases in Human Leucocytes and Platelets", <i>Scand. J. Haematol.</i> , <u>32</u> (1):25-32; (1984)
	BY	Dzau <i>et al.</i> , "Gene therapy for cardiovascular disease", <i>TIBTECH</i> , <u>11</u> (5):205-210; (1993)
	BZ	Eck <i>et al.</i> , "Structure of TNF- $\alpha$ : Implications for Receptor Binding", <i>J. Biol. Chem.</i> , <u>26</u> :17605; (1989)

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CA	Edwards <i>et al.</i> , "Inhibition of elastase by a synthetic cotton-bound serine protease inhibitor: in vitro kinetics and inhibitor release", <i>Wound Repair Regen.</i> , <u>7</u> (2):106-118; (1999)
CB	Erickson <i>et al.</i> , "Design, Activity, and 2.8 Å Crystal Structure of a C <sub>2</sub> Symmetric Inhibitor Complexed to HIV-1 Protease", <i>Science</i> , <u>249</u> :527-533; (1990)
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	FILING DATE February 2, 2001	GROUP 1614

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